REMARKS

Applicant respectfully requests consideration of these remarks and examination of the pending claims 19-39 and 46, 47, 49 and 50.

Claim Amendments

Claims 28, 30, 46, and 47 have been amended as will be discussed below.

In addition, claim 30 is clarified by amendment to correct a typographical error and replace the word "value" with "valve."

No new matter is added by any of these amendments.

Rejections Under 35 U.S.C. § 102

Claims 19-24, 27-35, 38-39 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 6,458,153 to Bailey. Applicant respectfully traverses this rejection.

With regards to independent claim 19, Bailey fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body that tapers linearly from the valve body second end to the valve body first end. The valve body (12) of the stent (12) of Bailey comprises a proximal anchor flange (22) at the first end of the body, an intermediate section (20) that has a constant diameter annular section extending from the first end, a tapered transitional section (18) extending from the intermediate section and a distal anchor section (16) that has a constant diameter annular cross-section extending to the second end of the body.

The prosthesis of Bailey must have the constant diameter of the intermediate section (20) accurately sized to suit the size of the native valve orifice which will vary from individual to individual. The prosthesis must then be accurately placed within the native valve orifice such that the intermediate section (20) is positioned precisely within the native valve orifice to engage the walls thereof. With the linearly tapering body of the prosthesis of the present invention as defined in claim 19, however, the tapering body will suitably fit any sized valve orifice having a diameter of between that of the first and second ends of the valve body. The valve body thus effectively acts as a linearly tapering plug which can be drawn towards and partly through the valve orifice with the valve body first end leading, lodging the valve body in the valve orifice at a location extending partly through the valve orifice.

Each of dependent claims 20 to 24 and 27 to 29 is patentable over Bailey at least by virtue of the fact that they are each dependent from patentable claim 19.

Claim 22 is further patentable over Bailey by virtue of the fact that Bailey fails to teach or suggest sub-frame members of the valve body having the general form of a deltoid with each deltoid having acute-angle vertices at the valve body first and second ends. None of the sub-frame members of the valve body of the Bailey prosthesis have acute-angle vertices both at the first and second ends of the valve body.

Considering claim 28, Applicant has amended claim 28 to refer to “barbs” instead of “prongs.” Applicant notes that support for this amendment can be found, as one example, at page 10, lines 22-28 of the originally filed PCT application. No new matter has been added by this amendment.

Bailey also fails to teach or suggest a plurality of barbs, as now included in amended claim 28, spaced around the periphery of the valve body second end (that is, the broader end). The flange elements (22) of Bailey do not constitute barbs, which include pointed backward facing projections to make extraction difficult. The flange elements (22) are also not positioned at the broader (second) end of the valve body.

With regards to independent claim 30, Bailey fails to teach or suggest a percutaneous heart valve prosthesis having a plurality of barbs spaced about a periphery of the broader (second) end of a tapered valve body as noted above in relation to claim 28.

Each of claims 31-35, 38 and 39 are also patentable over Bailey at least by virtue of the fact that they are each dependent from patentable claim 30.

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Claims 19-24, 27-28, 30-35, 38 were rejected under 35 USC 102(b) as anticipated by U.S. Patent Publication No. 2005/0043790 to Seguin. Applicant respectfully traverses this rejection.

With regards to independent claim 19, Seguin fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body that tapers linearly from the valve body second end to the valve body first end. The valve body of the stent (2) of the prosthesis of Seguin comprises a broad frustoconical proximal portion (10), a proximal cylindrical portion (11) and a narrow distal frustoconical portion (12). Whilst the first (distal) end of the body is narrower than the second (proximal) end of the valve body, there is no linear taper between these two ends. This configuration suffers from similar deficiencies to

those noted above in relation to Bailey. The stent of Seguin must be specifically sized for the proximal cylindrical portion (11) to suit the size of the native valve orifice. The stent must also be accurately placed to locate the proximal cylindrical portion (11) precisely in the native valve orifice.

Each of dependent claims 20 through 24, 27 and 28 are patentable at least by virtue of the fact that they are each dependent on patentable claim 19.

Claim 22 is further distinguished from the disclosure of Seguin, which fails to teach or suggest any sub-frame members in the general form of a deltoid having acute-angle vertices at both the valve body first (i.e., narrower) and second (i.e., broader) ends.

Claim 27 is further distinguished from Sequin, which fails to teach or suggest a mitral valve prosthesis. The prosthesis of Seguin is clearly described in terms of a prosthetic valve to be placed in a lumen of the body, in particular an aortic valve. A replacement mitral valve prosthesis is not intended to be placed in a lumen.

Claim 28 is further distinguished from Seguin, which fails to teach or suggest locating prongs spaced about a periphery of the valve body second (that is, broader) end. The hooks (15) of Seguin are located on the central cylindrical portion (11).

New dependent claim 49 is also further distinguished from Seguin, as Seguin fails to teach or suggest valve elements that block blood flow in the direction through the passage of the valve body from the valve body second end (that is the broader end) to the valve body first end (that is the narrower end).

With regards to independent claim 30, Applicant has amended claim 30 to refer to “barbs” instead of “prongs.” Applicant notes that support for this amendment can be

found, as one example, at page 10, lines 22-28 of the originally filed PCT application. No new matter has been added by this amendment.

Seguin fails to teach or suggest the provision of barbs spaced about a periphery of the valve body second (that is broader) end as noted above in relation to claim 28. The hooks (15) are located on the central cylindrical portion (11) of the body of the stent (2).

Each of claims 31-35 and 38 are patentable over Seguin at least by virtue of the fact that they are each dependent upon patentable claim 30.

Claim 38 is further distinguished from Seguin, which as noted above in relation to claim 27 fails to teach or suggest a mitral valve prosthesis.

New dependent claim 50 is also further distinguished from Seguin, which fails to teach or suggest blocking of blood flow in a direction through the passage of the valve body from the valve body second (i.e., broader) end to the valve body first (i.e., narrower) end as noted above in relation to claim 49. The valve (4) of the Seguin prosthesis allows blood flow from the second (broader) end to the first (narrower) end, and blocks flow in the opposing direction.

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Claims 19-20 and 22-26 were rejected under 35 USC 102(b) as anticipated by U.S. Patent Publication No. 2003/0014104 to Cribier. Applicant respectfully traverses this rejection.

With regards to independent claim 19, Cribier fails to teach or suggest a percutaneous heart valve prosthesis comprising a valve body that tapers linearly from the

valve body second end to the valve body first end. Contrary to the Examiner's assertions, the valve body (1) of the Cribier prosthesis does not taper from one end to the second end. Paragraph 41 of Cribier relied on by the Examiner states that "the frame has projecting curved extremities and presents a concave shape". A concave shape clearly suggests a double tapered or hourglass type of configuration, which is consistent with the arrangement depicted in Figure 3b, described in the Brief Description of the Drawings as having the concave shape. It is clear that this arrangement does not taper from one end to the other. Each of the remaining configurations of the prosthesis of Cribier has a generally cylindrical body.

Each of dependent claims 20 and 22-26 is patentable in view of Cribier at least by virtue of the fact that these claims are each dependent from patentable claim 19.

Claim 22 is further distinguished from the disclosure of Cribier, which fails to teach or suggest sub-frame members of the valve body having the general form of a deltoid having acute-angle vertices at the valve body first and second ends.

Claim 25 is further distinguished from the disclosure of Cribier, which fails to teach or suggest a collapsible diagonal element extending between oblique-angle vertices. It is evident from Figure 4b that the rectilinear struts (17) referred to by the Examiner extend longitudinally between the first and second ends of the valve body, a distance away from the oblique-angle vertices of the individual sub-frame elements, rather than extending between oblique-angle vertices.

<u>The rejections under 35 USC 103.</u>

Claims 30-38 were rejected under 35 USC 103(a) as being unpatentable over Cribier in view of U.S. Patent Publication No. 2004/0093060 to Seguin et al. Applicant respectfully traverses this rejection.

Contrary to the Examiner's assertions, Cribier does not disclose all of the claim limitations of these claims except for a plurality of prongs spaced about a periphery of the valve body second (that is, broader) end. As noted above in relation to claim 22, Cribier fails to teach or suggest a valve body that tapers towards the valve body first end. The valve body of the Cribier prosthesis as depicted in Figure 3b tapers from each of the ends towards the centre of the prosthesis. Further, as noted above, Seguin fails to teach or suggest provision of a plurality of prongs spaced about a periphery of a valve body second (that is, broader) end. No combination of Cribier and Seguin teaches each of the limitations of independent claim 30 or any of its dependent claims 31 through 38.

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Claims 46-47 were rejected under 35 USC 103(a) as unpatentable over Bailey in view of U.S. Patent Publication No. 2004/0039442 to Goar.

Contrary to the Examiner's assertions, as discussed above, Bailey fails to teach or suggest a device having each of the claim limitations of either of claims 19 and 20.

Further, the only prosthesis of Bailey that is utilised to treat a failed or failing mitral valve is the stent valve (40) depicted in Figures 12a and 12b referred to by the Examiner. This stent valve is depicted in greater detail in Figures 7 to 11 as having a valve body member (12) having a substantially cylindrical central section and proximal and distal

anchor flanges (44, 42) formed at the first and second ends of the valve body member (12).

Further, neither Bailey nor Goar suggest locating a prosthesis in the catheter with the valve body second (that is, broader) end located between the valve body first (i.e., narrower) end and the catheter first (i.e., leading) end. As noted above, the mitral valve stent (40) of Bailey is not tapered so as to distinguish between a broader (i.e., second) end and a narrower (i.e., first) end of the valve body.

Further, in the method depicted in Figure 20, the valve body first (i.e., narrower) end is positioned between the valve body second (i.e., broader) end and the catheter first (i.e., leading) end. Further, considering claim 47, neither Bailey nor Goar suggest engaging barbs with cardiac structure surrounding an end of the native valve orifice.

New Claims.

Applicant has added new dependent claims 49 and 50. Both of these claims depend upon an allowable independent claim. No new matter has been added. Applicant respectfully requests entry of claims 49 and 50.

Information Disclosure Statement

Being submitted concurrently with this response is an information disclosure statement.

CLOSING

Applicant has amended claims 28, 30, 46 and 47, and added new claims 49 and 50. Examination of pending claims 19-39, 46, 47, 49 and 50 is respectfully requested. It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede any basis for rejections or objections in the Office Action. Further, with regards to the various statements made in the Office Action concerning any prior art, the teachings of any prior art are to be interpreted under the law. Applicant makes no admissions as to any prior art. The remarks herein are provided simply to overcome the rejections and objections made in the Office Action in an expedient fashion.

The undersigned welcomes a telephonic interview with the Examiner, if the Examiner believes that such an interview would facilitate resolution of any outstanding issues.

Respectfully submitted

By: /John V. Daniluck/

John V. Daniluck
Reg. No. 40,581
Bingham McHale LLP
2700 Market Tower
10 West Market Street
Indianapolis, Indiana 46204
(317) 968-5529 (telephone)
(317) 236-9907 (facsimile)